K010707

MAR 2 9 2001

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Boston Scientific Scimed (BSS) Atlantis™ SR Plus Coronary Intravascular Ultrasound Imaging Catheter

Summary of Safety and Effectiveness:

Submitted by:

Boston Scientific Scimed
IVUS Technology Center
47900 Bayside Parkway
Fremont, CA 94538

Contact Person:

Irene Jaworski
Manager Regulatory Affairs
(510) 624-1580

Date prepared:

March 8, 2001

Proprietary Name:

Atlantis™ SR Plus

Common Name(s):

Ultrasound Diagnostic Imaging Catheter
Diagnostic Ultrasonic Transducer (90 ITX)
Diagnostic Intravascular Catheter (74 DQO)

Classification Name(s):

Diagnostic Ultrasonic Transducer, 21 CFR Part 892.1570, (90 ITX); and Diagnostic Intravascular Catheter, 21 CFR Part 870.1200, (74 DQO);

Predicate Device:

The BSS Atlantis™ SR Plus coronary imaging catheter is substantially equivalent to the following predicate device:

Product	510(k)	Clearance Date
Atlantis™ SR Coronary Imaging Catheter	K000743	Sept. 6, 2000

Description of the Device:

The BSS Atlantis™ SR Plus coronary imaging catheter consists of two main assemblies:

- imaging core
- catheter body

The catheter body is comprised of three sections:

- distal lumen
- proximal lumen
- telescoping section

The distal lumen and proximal lumen sections comprise the "working length" of the catheter, and the telescoping section remains outside of the guiding catheter. The telescoping shaft (section) allows the imaging core to be advanced and retracted for 15 cm of linear movement. The corresponding movement of the transducer occurs from the proximal end of the wire exit port, to the proximal end of the distal lumen.

The imaging core is composed of a flexible, rotating drive cable with an radially looking 40 MHz ultrasonic transducer at the distal tip. An electro-mechanical connector interface at the proximal end makes the connection to the MotorDrive Unit (MDU) / Instrument. The MDU-Catheter interface consists of an integrated mechanical drive hub and electrical connection.

A flush port with a one-way valve is used to displace air near the transducer. The catheter must be flushed with heparinized saline prior to use, as this provides the acoustic coupling media required for ultrasonic imaging. The one-way valve helps retain saline in the catheter during use.

The catheter body has a distal guidewire lumen with proximal exit port at approximately 1.5 cm from the distal end. The catheter body is attached to the telescope shaft via a male/female luer connection. A radiopaque (RO) marker is embedded in the catheter body at 0.5 cm from the distal tip. In addition, an insertion depth indicator is located on the catheter body at 105 cm, corresponding to femoral insertions. The catheter is for use with the BSS ClearView Ultra™ System, with High Frequency Option.

Intended Use/Indications:

The BSS Atlantis™ SR Plus coronary imaging catheter is intended for ultrasound examination of coronary intravascular pathology ONLY. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

Device Technological Characteristics and Comparison to Predicate Device:

The BSS Atlantis™ SR Plus coronary imaging catheter utilizes the same basic catheter design as the predicate device, the BSS Atlantis™ SR coronary imaging catheter. The imaging core of both devices is the same. The materials incorporated in both devices are the same. Both devices have the same shelf life, and are packaged and sterilized using the same materials and processes. The difference between the two devices lies in dimensional changes in the distal tip profile of the catheter body. The BSS Atlantis™ SR Plus coronary imaging catheter has a reduced imaging window profile, reduced RO profile, a tapered entry profile and reduced internal diameter of the guide wire lumen. These dimensional changes are made to enhance catheter performance.

Performance Data:

Performance testing for the BSS Atlantis™ SR Plus coronary imaging catheter demonstrated that the device meets or exceeds the performance requirements for the intended clinical use of the device. The test results of the BSS Atlantis™ SR Plus coronary imaging catheter were found to be comparable to those of the predicate device, the BSS Atlantis™ SR coronary imaging catheter.

Laboratory testing included dimensional testing, sheath bond tensile testing, and a variety of functional performance tests.

Conclusion:

The BSS Atlantis™ SR Plus coronary imaging catheter utilizes the same design and has the same intended use as that of the predicate device, BSS Atlantis™ SR coronary imaging catheter. The performance data and a Declaration of Conformity with Design Controls support a determination of substantial equivalence of the modified device, the BSS Atlantis™ SR Plus coronary imaging catheter to the predicate device, the BSS Atlantis™ SR coronary imaging catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2001

Ms. Irene Jaworski
Boston Scientific Corporation
IVUS Technology Center
47900 Bayside Parkway
Fremont, CA 94538

Re: K010707
Trade Name: Atlantis™ SR Plus Coronary Imaging Catheter
Regulatory Class: II (two)
Product Code: DQO and ITX
Dated: March 8, 2001
Received: March 9, 2001

Dear Ms. Jaworski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the BSC ClearView® Ultra™ product line and Galaxy™ product line, as described in your premarket notification:

Transducer Model Number 35975

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Lesley Ewing at (301) 443-8320, ext 161.

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K010707

Device name: **Boston Scientific Scimed Atlantis™ SR Plus Coronary Imaging Catheter**

Indications for Use: The BSS Atlantis™ SR Plus coronary imaging catheter is intended for ultrasound examination of coronary intravascular pathology ONLY. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010707

Prescription Use λ OR Over The Counter Use_____
(Per 21 CFR 801.109)